UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,635	01/13/2006	Elger Funda	4662-121	2120

23117 7590 02/16/2010

NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER	
GREENE, IVAN A	

ART UNIT	PAPER NUMBER
1619	

MAIL DATE	DELIVERY MODE
02/16/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,635	FUNDA ET AL.	
	Examiner	Art Unit	
	IVAN GREENE	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/28/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the claims

Claims 1-21 are currently pending and are presented for examination on the merits.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/28/2009 has been entered.

All rejections and/or objections not explicitly maintained in the instant office action have been withdrawn per Applicants' claim amendments and/or persuasive arguments.

The U.S. effective filing date has been determined to be 07/06/2004, the filing date of the document PCT/EP04/07367.

The information disclosure statement(s) submitted on 12/28/2009 was filed before the mailing of a first office action after the filing of a request for continued examination under. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the Examiner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 1-21 remain rejected under 35 U.S.C. 103(a) as being unpatentable over SCHNEIDER (US 5,356,636) in view of BEWERT (EP 0982038), KODERA (US 6,455,273) and ARIA (US 4,921,705); and as evidenced by GERRARD (Trends in Food Science and Technology, 13, 2002, pgs. 391-399) and HAMAGUCHI (US 5,127,953).

Applicants claim

Applicants claim stable powderous formulations comprising a fat-soluble active ingredient in a matrix of a native or partially hydrolyzed milk protein composition, wherein the protein is thermally cross-linked with a reducing sugar or a desoxy sugar or an amino sugar. Applicants further claim the stable powderous milk protein composition comprises a plant protein with an average molecular weight below 2500 Daltons. Applicants further claim the stable powderous milk protein composition wherein the fat-soluble active ingredient is vitamin A, D, E or K, or a carotenoid, or a polyunsaturated fatty acid, or ester thereof. Applicants further claim food, beverages, animal feeds, cosmetics or drugs comprising the aforementioned milk protein formulations. Applicants further claim a process for preparing milk protein formulations comprising: preparing an aqueous emulsion of the fat-soluble active ingredient and the milk protein composition, adding a reducing sugar, converting the emulsion into a dry powder and submitting the dry powder to cross-linking the protein by heat treatment.

Determination of the scope and content

of the prior art (MPEP 2141.01)

SCHNEIDER teaches a process for preparing stable dry powders which are insoluble in hot water and which contain fat-soluble vitamins and/or carotenoids comprising preparing an aqueous emulsion of the fat-soluble active ingredient, a film-forming colloid (gelatin) and a reducing sugar, converting the emulsion into a dry powder and submitting the dry powder to cross-linking of the proteins by heat treatment (abstract).

SCHNEIDER further teaches, "The fat-soluble vitamins include vitamins A, E, D and K as well as mixtures thereof. For the purpose of the present invention they can be employed in the form of vitamin solutions in oils...Particularly interesting products contain vitamin A and its derivatives, especially vitamin A acetate, vitamin A palmitate..." (3:59-66). SCHNEIDER further teaches the sugars can be any reducing sugars or syrup containing reducing sugars including fructose, glucose, lactose, maltose, xylose, arabinose, ribose and invert sugar (4:11-17). SCHNEIDER further teaches, "In addition to the obligatory ingredients, it is advantageous to add to the dispersion other compounds customary in the preparation of active substance dry powders" (4:59-63). SCHNEIDER goes on to teach the additives starch, maltodextrin, alginates (5:8-9) and hydrophobic silica (4:42).

Examiner notes SCHNEIDER teaches that casein does not form thermo-reversible gels (3:3-8), but may be obtained as fine water-dispersible particles. This teaching is not considered teaching away from the use of casein because SCHNEIDER does not suggest that casein could not be used in the process they describe. Examiner further notes the prior art which teaches modified protein food additives often suggest the use of gelatin or casein; see BEWERT ([0017]), ARIA (2:52-58); HAMAGUCHI (4:39-45).

Ascertainment of the difference between the

prior art and the claims (MPEP 2141.02)

The difference between the rejected claims and the teachings of SCHNEIDER is that SCHNEIDER does not expressly teach milk proteins; addition of a plant protein

hydrolysate with an average molecular weight of less than 2500 Daltons; or vegetable oil(s), such as sunflower, palm or corn oil. The deficiency of using the milk protein casein is cured by BEWERT. The deficiency of the addition of a plant protein or plant protein hydrolysate is cured by the teachings of KODERA. The deficiency in sunflower and/or palm oil(s) is cured by the teachings of ARIA.

BEWERT teaches dry powder formulations comprising fat-soluble active ingredients in a cross-linked protein matrix ([0001]). BEWERT further teaches the preferred proteins are gelatin, casein, soy protein, corn protein and collagen ([0017]). BEWERT further teaches the release agents silicic acid and corn starch ([0022]). BEWERT further teaches the preferred cross-linking agent is the enzyme transglutaminase ([0026]). BEWERT further teaches preferable fat-soluble active ingredients are vitamin of the group A, D, E and K, or carotenoids ([0027]).

Examiner notes, BEWERT suggests the disadvantages for cross-linking with a reducing sugar using heat treatment are degradation of the active ingredient and browning of the final product; however, from the prior it is clear that there are both advantages and disadvantages for cross-linking base on heat treatment vs. chemical or enzymatic treatment. For example, cross-linking using aldehydes or ketones, may cause residual cross-linking with time. GERRARD suggests the use of enzymes is favored by consumers as more “natural” and they require milder conditions to act; however, the disadvantage of enzymes is their higher cost vs. thermal and chemical cross-linking approaches. Chemical modification of food products, while more cost effective, is not desirable because of harsh reaction conditions, non-specific chemical

reaction reagents and difficulty of removing chemical reaction reagents from the final product.

KODERA teaches a method for producing a protein hydrolysate with low bitterness (abstract) for use in foodstuffs, infant formulas, medicinal diets, seasonings, flavor-modifying materials, food-property modifying materials, food additives and feeds (2:10-20). KODERA further teaches, the protein substrate for their invention is preferably a vegetable protein, such as, soy bean or gluten or an animal protein such as casein or gelatin (4:8-18). KODERA further teaches the range of the molecular weights of the protein hydrolysate is preferably 200 to 2000 Daltons (4:28-32). KODERA further teaches the product of their invention can be used by incorporation into a variety of food products (4:56-63).

ARIA teaches a lipid powder having a cross-linked coating thereon comprising a core lipid powder and a cross-linked protein coating (abstract). ARIA further teaches the lipid core may include vegetable oils, palm oil and/or sunflower oil(s) (2:28-32).

As to the claimed dextrose equivalents of the starch hydrolysates, where the claimed prior art products are substantially identical in structure or composition or are produced by identical or substantially identical processes a prima facie case of either anticipation or obviousness has been established. Absent evidence to the contrary the prior art composition must posses the claimed dextrose equivalents since it is substantially identical to the claimed composition (See MPEP 2112.01).

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the stable dry powder of SCHNEIDER with the stable dry powder based on casein of BEWERT because they both teach stable dry powdered food additives containing a fat-soluble vitamin ingredients. The skilled artisan would have been motivated to use casein in the invention of SCHNEIDER because the milk protein would have provided improved nutritional value for mammals.

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the stable dry powder of SCHNEIDER with the plant protein hydrolysate of KODERA because it would produce a more nutritive food additive. Furthermore, a plant protein with a low average molecular weight would provide for a more easily ingestible food product as taught by KODERA (2:13).

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to combine ARIA with SCHNEIDER and produce a stable dry powder comprising an vitamin A acetate and an vegetable oil such as palm oil because vitamin A acetate is a lipid soluble vitamin and would have easily dissolved in the oil. The skilled artisan would have been motivated to combine the vegetable oil of ARIA with the oil soluble vitamins of SCHNEIDER because the oil-diluted vitamin A acetate would have been easier to handle and process, and the vegetable oil(s) such as palm and/or sunflower oil would have been inexpensive and readily available.

The processing of foods, which is common place in modern society, provides for an increased shelf life, consistent and appealing texture, and enhanced flavor. Cross-linking of proteins provides a means for controlling the functional properties of foods,

such as the texture. A cross-linked protein can also provide a matrix for additional beneficial ingredients such as fat-soluble vitamins. A dry powdered product would be very desirable for functional proteins for use as food additives because the storage conditions would be more favorable and the shipping costs would be reduced. It would have been prima facie obvious that vitamin enrichment would provide for a more nutritious and therefore desirable product.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success , for example the prior art teaches cross-linking of different proteins using various methods, as discussed above. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments:

Applicant's arguments filed 04/15/2009 have been fully considered but they are not persuasive.

Applicant's argument that casein is a globular protein without a secondary and tertiary protein structure [which distinguishes it from] gelatin which is a fibrous protein having a triple helix structure, is acknowledged. First, Applicant's reliance on Wikipedia definitions is ineffective because anyone with access to the internet can write and make

changes to Wikipedia, thus *the definitions can be changed by any user*. And in this case the definitions clearly have been changed because the Wikipedia definition for casein makes no mention of "globular proteins" and the Wikipedia definition for gelatin makes no mention of "long protein filament, rod or wire like shapes" (See Wikipedia documents: "about Wikipedia," and entries for casein and gelatin, attached). Applicant's reliance on Wikipedia not withstanding, the structural differences between casein and gelatin would not have lead a person having ordinary skill in the art to conclude that casein could not have been used in the invention of because the prior art clearly teaches the functional equivalence of casein and gelatin: BEWERT teaches:

> [0001] The current invention concerns active substance preparing, an embedded with which or several active ingredients are into a protein matrix, whereby the proteins with transglutaminase are transversecrosslinked. The active substance preparing e.g. lie. as stable dry powders forwards. The invention relates to in addition food and feed contained such preparing, methods to the preparation of the dry powders and particular uses of the transversecrosslinked proteins. In the special one the invention concerns dry powders, the vitamins, food and feed additives, like e.g. Carotenoids contain. In addition various additives can be embedded.
> [0017] Prefered crosslinkable proteins are *gelatin, casein,* Soja protein, corn protein and collagen. [emphasis added]

ARIA teaches:

> [57] **ABSTRACT**
>
> A lipid powder having a cross-linked coating thereon comprises a core lipid powder and a water-soluble coating agent coating the core lipid powder. The water-soluble coating agent contains cross-linked protein.

And at column 2:

It is essential that the cross-linked protein be contained in the water-soluble coating agent employed in the present invention. Examples of the protein may include milk protein such as casein, sodium caseinate or lactoalbumin, egg protein such as egg white albumin or ovomucoid, and animal protein such as collagen or gelatin.

HAMAGUCHI teaches (col. 3):

SUMMARY OF THE INVENTION

With a view toward developing a powdery fat or oil product free from the above-mentioned problems, the present inventor has made extensive and intensive studies. As a result, it has unexpectedly been found that by mixing a fat or oil, a base material capable of occlusion or absorption of the fat or oil and a polyol having at least two hydroxyl groups in specific proportions while agitating at a temperature at which the fat or oil melts, a unique powdery or granular fat or oil composition can be obtained, in which the fat or oil is occluded or absorbed in the base material. Such a powdery or granular

And at column 4:

As the base material, there may be employed a substance capable of inclusion of a fat or oil by occlusion or absorption. A hydrophilic substance capable of occlusion or absorption of a fat or oil may preferably by employed. Examples of hydrophilic substances usable as the base material include hydrophilic proteins such as gelatin, casein, sodium caseinate, whey protein and

There is no doubt that there are structural and/or functional differences between casein and gelatin. However, as evidenced by the prior art, these differences would not have discouraged a person having ordinary skill in the art from following the path which leads from gelatin to casein. In this regard, the teachings of ALLEGRETTI are pertinent. ALLEGRETTI teaches:

> ings." It has also been suggested to encase the vitamin in materials such as gelatin or colloidal substances. Many techniques of making oxygen-impervious gelatin coatings have been studied and described. Gelatin alone has been employed as a coating agent, and attempts to increase stability by utilization of certain synthetic resinous materials along with gelatin are known. Most of these approaches have led to products or compositions which are more stable than the vitamin A esters themselves, but there is still difficulty in obtaining a completely satisfactory material.
>
> It is an object of the present invention to provide a highly stable form of vitamin A suitable for addition directly to animal feed supplements or to pharmaceutical products. It is a further object to provide a dry free-flowing powder containing vitamin A activity in which the vitamin activity is highly stable. An additional object is provision of stable vitamin A compositions in which a vitamin A ester is the source of vitamin activity. Another object is a process for making such compositions. Further objects will be apparent from the detailed description of the invention hereinbelow.
>
> According to my invention highly stable vitamin A-active compositions are prepared by reacting together formaldehyde and partially hydrolyzed casein in the presence of a vitamin A ester. The partially hydrolyzed casein and formaldehyde react to form a solid to semi-solid

Moving from the suggestion to use gelatin in the prior art to using casein. Therefore, based upon the teachings of the prior art a person having ordinary skill in the art would not have been discouraged from moving from the gelatin taught by SCHNEIDER to the casein taught by BEWERT and ARIA.

Applicant's argument that Schneider is quite clear in preferring gelatin and teaching away from the use of other materials, in particular casein, is not convincing because SCHNEIDER teaches the preferred embodiment of their invention is directed to "…stable dry powders *which are insoluble in hot water*..." (1:6-7, [emphasis added]), and the teaching in SCHNEIDER that applicant has asserted teaches away from the instantly clamed invention:

> Although the use of amino acids and reducing sugars for preparing formulations in powder form of fat-soluble vitamins and the drying thereof on exposure to heat is described in JA-B 45-38348 (published 1970), this describes only vitamin powders based on alkali metal salts of casein, but not on gelatin. However, since casein, in contrast to gelatin, does not form thermo-reversible gels it is only possible in this way to obtain very fine-particle products which are not very suitable, for example, for use under hydrothermal stress because they are dispersible in water.

(2:66-68; 3:1-8) is simply distinguishing the invention of SCHNEIDER from the prior art document JP S45-38348. SCHNEIDER distinguishes their invention by pointing out that the casein *products* of JP S45-38348 *are not very suitable for use under hydrothermal stress* which is *not a contemplated embodiment of the instant invention, as currently clamed*. Furthermore the teaching that casein products are not very suitable for the

invention of SCHNEIDER does not constitute a teaching away because disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments (MPEP § 2123 - II). The examiner has included a Japanese language copy of the cited document JP S45-38348 and ordered an English language translation which will be forwarded to Applicant for consideration.

Nonstatutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1, 12-14, 16 and 17 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7-9, 11 and 13 of copending Application No. 10/551,197 (hereafter referred to as '197) in view of BEWERT and DOXASTAKIS (Novel Macromolecules in Food Systems, pgs 7-38).

Instant claim 1 recites, stable powderous formulations comprising a fat-soluble active ingredient in a matrix of milk protein compositions, wherein the protein is thermally cross-linked with a reducing-sugar. Copending '197 claim 1 recites, stable powderous formulations comprising a fat-soluble active ingredient in a matrix of native lupin protein composition wherein the protein is cross-linked; copending '197 claim 11 recites, a process wherein a reducing sugar is added and the composition is submitted cross-linking by heating. The difference between the claim of copending '197 and the instant claimed invention is the primary cross-linking protein.

Instant claims 12 recites, formulations wherein the fat-soluble active ingredient is vitamin A, D, E or K, or a carotenoid, or a polyunsaturated fatty acid; instant claim 13 recites formulations wherein the fat-soluble active ingredient is mixed with a plant or animal fat. Copending '197 claim 6 recites, formulations wherein the fat-soluble active ingredient is vitamin A, D, E or K, or carotenoids, or a polyunsaturated fatty acid; copending '197 claim 7 recites form formulations wherein the fat-soluble active ingredient is mixed with a plant or animal fat. Instant claims 12 and 13 are coextensive in scope with copending '197 claims 6 and 7.

Instant claim 14 recites, formulations wherein the reducing sugar is glucose, fructose, saccharose, or xylose. Copending '197 claim 8 recites, formulations wherein the reducing sugar is glucose, fructose, saccharose, or xylose. Instant claim 14 is coextensive in scope with copending '197 claim 8.

Instant claim 17 recites, a process for the preparation of formulations comprising preparing an aqueous emulsion of the fat-soluble active ingredient and the milk protein composition, adding the reducing sugar, converting the emulsion into a dry powder, and submitting the dry powder to cross-linking the protein with heat treatment. Copending '197 claim 13 recites, a process for the preparation of formulations comprising preparing an aqueous emulsion of the fat-soluble active ingredient and the native lupin protein composition, adding the reducing sugar, converting the emulsion into a dry powder, and submitting the dry powder to cross-linking the protein by heat treatment or by treatment with a cross-linking enzyme. The difference between instant claim 17 and copending

‘197 claim 13 is the primary cross-linking protein and the alternative possibility of enzymatic cross-linking copending ‘197 claim 13.

The difference between Copending ‘197 and the instant claimed invention is that copending '197 does not explicitly teach the use of native milk protein for the primary cross-linking protein. The deficiency of using a native milk protein is cured by the teachings of BEWERT.

BEWERT teaches dry powder formulations comprising fat-soluble active ingredients in a cross-linked protein matrix wherein the preferred protein is casein, as discussed above. BEWERT further teaches, preferred cross-linkable proteins are gelatin, casein, soy protein, corn protein and collagen ([0017]). DOXASTAKIS teaches lupins belong to the legume group of plants and are able to grow in marginal soils, enabling the plant to grow in many environments (pg. 7, lines 1-6). DOXASTAKIS further teaches, "Interest in a wider utilization of lupin seeds is mainly due to its similarity to soybeans as a high source of protein and to the fact that it can be grown in more temperate climates and is tolerant of poor soils (pg. 7, lines 18-20). .

It would have been prima facie obvious to combine copending ‘197 with the teachings of BEWERT and produce the instant claimed invention because both copending ‘197 and BEWERT teach dry powdered food additives with cross-linked protein and a fat-soluble active ingredient in the protein matrix. It is prima facie obvious to combine similar compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose, i.e. a stable dry vitamin powder. See MPEP 2144.06.

It would have been prima facie obvious to combine copending '197 with the teachings of DOXASTAKIS and BEWERT because BEWERT teaches that casein and soy can be used interchangeably with their invention and DOXASTAKIS teaches that lupins are a viable alternative to soybeans. Examiner notes the comprising language of copending ‘197 invites additional ingredients.

This is a provisional obviousness-type double patenting rejection.

The examiner acknowledges applicant's wish to hold the foregoing provisional obvious-type double patenting rejection in abeyance until allowable subject matter is

indicated. Applicant is advised that the Patent Office does not hold either objections or rejections in abeyance, therefore the rejection is maintained.

Conclusion

The following U.S. Patent documents are not relied upon but made of record because they are considered pertinent to applicant's disclosure: ALLEGRETTI (US 2,897,118), particularly (1:38-63); RUSOFF (US 2,835,592), particularly (1:40-45, 52-64; 2:43-51; 3:58-75; 1:1-2, 35); SCIALPI (US 4,670,247), particularly (columns 1-2; 4:46-51; 5:3-8); HIESTAND (US 3,549,555) whole document; and SCHMIDT (US 4,395,422) whole document.

The following Japanese Patent document is not relied upon but made of record because it considered pertinent to applicant's disclosure: JP S45-38348 (an English language translation has been ordered and will be forwarded to Applicant upon receipt).

The following non-patent literature documents are not relied upon but made of record because they are considered pertinent to applicant's disclosure: Merck Index entries for casein and gelatin; Hawley's Condensed Chemical Dictionary, entries for casein and gelatin; SINGH (Trends in Food Science & Technology, 1991, vol. 2, pp. 196-200); MOTOKI (Trends in Food Science & Technology, 1998, vol. 9, pp. 204-210); WHITEHURST ("Enzymes in Food Technology," CRC PRESS, 2002, pp. 109-143), particularly pages 138-140); HUI ("Handbook of Food Science, Technology, and Engineering - Volume 2," CRC PRESS, 2006, Chapter 83).

Claims 1-21 are pending and have been presented for examination on the merits. The Specification is objected. Claims 1-21 are rejected under 35 USC § 103(a); and

claims are provisionally rejected on the grounds of nonstatutory obvious-type double patenting over copending 10/551,197. No claims allowed at this time.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IVAN GREENE whose telephone number is (571)270-5868. The examiner can normally be reached on Monday through Thursday 7AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bonnie Eyler can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

IVAN GREENE
Examiner, Art Unit 1619

/YVONNE L. EYLER/
Supervisory Patent Examiner, Art Unit 1619